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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/077,232	02/15/2002	Kathryn F. Sykes	UTSD:557USD1/MBW	5365

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09/24/2003

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EXAMINER

AKHAVAN, RAMIN

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 09/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Applicant

Office Action Summary

Application No.

10/077,232

Applicant(s)

SYKES ET AL.

Examiner

Ray Akhavan

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 97-122 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 97-122 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

DETAILED ACTION

Priority

This application appears to be a division of Application No. 09/535,366, filed 03/24/2000 which claims benefit of a provisional Application No. 60/125, 864 filed on 03/24/1999 and also claims benefit of a provisional Application No. 60/127,222 filed on 03/31/1999. A later application for a distinct or independent invention, carved out of a pending application and disclosing and claiming only subject matter disclosed in an earlier or parent application is known as a divisional application or "division." Furthermore, to perfect the claim for priority under §120, applicant is required to explicate the current status of all non-provisional applications, in the first sentence of the specification.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See Spec. at 30 ¶2 and 95 ¶2. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Objections

Claim 101-103 objected to because of the following informalities: the claims contain a nominal grammatical error, where the modifier of "antigen" in each claim is another noun instead of an adjective; written properly the claims should read "viral" instead of "virus" (claim 101); "bacterial" instead of "bacterium" (claim 102); and "fungal" instead of "fungus" (claim 103). Appropriate correction is required.

Claim 111 is objected to because it does not further limit claim 97; the claim recites the phrase where the “organism is an animal” and claim 97 recites the phrase “an animal”.

Claim 114 is grammatically incorrect because the noun and verb are not in agreement. The proper verb would be “comprise” and not “comprises”.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 97-122 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 97 recites the phrase “[o]pen reading frames that encode an antigen effective to generate an immune response.” It is unclear and indefinite if the claim as drafted is drawn to an immune response elicited by the DNA itself or expression of the encoded polypeptide or both in combination. The disclosure indicates that gene expression is necessary for antibodies to be raised against polypeptides (Spec. at 91, 93, Ex. 8 and 9), but does not teach whether the DNA or open reading frames themselves elicit an immune response. The claim could be rewritten with the nominal addition of the phrase “where said” in between the terms “antigen” and “effective” thus indicating clearly that the encoded polypeptide is necessary to elicit an immune response. All the remaining claims (98-122) depend from claim 97 thus are also rejected.

Claims 99, 104-106, 111 and 120 are improperly drafted because they refer to the “method” in claim 97, where claim 97 is actually drawn to a composition (a product by process claim). The proper reference should be the “composition” in claim 97. In addition claim 99

recites the term “pathogen antigen”. It is unclear and indefinite whether this means that an antigen from a pathogenic agent (e.g. bacteria) or whether this means an antigen that has pathogenic effects. The plain meaning of pathogen is an agent that causes disease, thus an antigen can be a pathogen exclusive of its source, so that a “pathogen antigen” could mean an antigen that is pathogenic or an antigen that is produced by a pathogenic organism. The claim would be unambiguous if it read “[O]ne or more antigen from a pathogen” which is presumably what the applicant intends, as reflected in claim 100. However, claim 100 is unclear and indefinite as drafted because the claim recites, “[O]ne or more pathogen antigen is a one or more virus...” It is unclear whether applicant means that the ‘whole’ organism from the class of recited organisms is the antigen or that any composition produced from the class of organisms recited in the claim is the antigen. In addition, in claim 100 the indefinite article “a” has no meaning in the context of the claim and should be omitted. An alternative drafting could be the claim as written in claim 115 which when referring to the antigen from a pathogen reads: “wherein the pathogen is a virus, bacterium...” Claims 100-103 depend from claim 99, thus are also rejected.

Claim 109 is vague and indefinite because the claim recites the phrase “open reading frames” (ORFs) when referring to linking of ORFs to “terminator”. Use of the plural – ORFs – makes the claim confusing; does applicant mean each ORF has a terminator or that only some ORFs have terminators attached.

Claim 110 and 111 recite the limitation “organism” in claim 97. There is insufficient antecedent basis for an organism in the claim because claim 97 recites the term “animal” which is actually narrower in scope than organism.

Claim 118 recites the phrase “testing the animal against challenge with pathogen” which is vague and indefinite. It is unclear if the organism to be tested comprises the plurality of expression elements. Furthermore it is unclear whether the pathogen is the ‘whole’ organism or products from such an organism.

Claim 122 recites the terms “effective” and “appropriate dosage” when referring to the composition in claim 97 but the disclosure does not define the terms effective or appropriate dosage. The specification does disclose a single example incorporating a gene gun, where mice are injected with 0.5ug (Spec. at 91, Ex. 7) of a linear expression element (LEEs) however this disclosure does not clarify what would be the proper dosage for animals, using either CEEs, LEEs or a combination of both. Moreover the example disclosed only shows that there is an immune response not whether the animal is “protected”. from a pathogen. See Spec. at 91 Ex. 7

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 97, 99-100, 102, 104-112, 114-115 and 118-122 are rejected under 35 U.S.C. §102(b) as being anticipated by Curtiss, III et al. U.S. 5,387,744 (Nov. 29, 1994)(Curtiss ‘744).

Claims 97-122 are drawn to “A composition comprising one or more antigen”. Claim 97 from which all other claims ultimately depend is a product-by-process claim, which is not limited by the manipulations of the recited steps but rather only limited to the structure or composition of the product, thus patentability is determined by the product itself and not a

method of production. See MPEP §2113. Put another way, applicant's invention is drawn to any composition that is an antigen (e.g. A substance that when introduced into the body stimulates the production of an antibody, including toxins, bacteria, foreign blood cells, and the cells of transplanted organs), thus is anticipated by any characterized antigen identified through any method. In the extreme case the claims are drawn to virtually anything under the sun that can induce an immune response in an animal. Subsequent claims that depend from claim 97 and add further limitations to the composition's structure will be addressed below, but dependent claims that only add further limitations to the process/method are not dispositive with regard to whether the claim is anticipated by any of the references cited, that teach an antigen or antigens (i.e. the product of claim 97).

Claims 97, 99-100, 102, 104-112, 114-115 and 118-122 are anticipated by Curtiss, III et al. U.S. 5,387,744 (Nov. 29, 1994)(Curtiss '744), which recites immunogenic compositions derived from a pathogen – a bacterium. See Abstract, Curtiss '744. The claims are drawn to antigen(s) that may be bacterial (claim 102) or otherwise contain modifications in the method of making/processing; as noted above limitations to the method are not dispositive as to whether the claims are anticipated. Claim 121 adds a further limitation to the composition: "comprised in a pharmaceutical composition", but such a limitation would be inherent for any composition that is intended for in vivo use (the art is replete with pharmaceutical compositions). Therefore Curtiss '744 anticipates said claims.

Claims 97-99 and 104-113 are anticipated by Chu et al. U.S. 4, 446, 122 (May 1, 1984) (Chu '122). The claims are drawn to antigen(s) from a cancer cell. Chu '122 teaches a purified

human prostate antigen which is expressed by cancer cells in the prostate. See Abstract, Chu '122. Therefore Chu '122 anticipates claims 97-99 and 104-113.

Claims 97, 99-101, 104-112 and 114-122 are anticipated by Parker et al. U.S. 5, 369, 026 (Feb. 7, 1995) (Parker '026). The claims are drawn to an antigen(s) that is a "virus antigen". Parker '026 teaches antigenic compositions that are viral. See Abstract, Parker '026. Therefore Parker '026 anticipates claims 97, 99-101, 104-112 and 114-122.

Claims 97, 99-100, 103-112, 114-115 and 118-122 are anticipated by Klein and Jones. Infec. Immunol. 62: 3890-3900 (1994). The claims are drawn to fungal antigen(s). Klein and Jones teach a major fungal antigen composition. See Abstract, Klein et al. Thus Klein et al. anticipates said claims.

Claim 97, 9-100, 104-112, 114-115 and 118-122 are anticipated by Wiedemann et al. JBC, 271(47): 29915-29921 (1996). The claims are drawn to antigen(s) from plants. Wiedemann et al. teach a plant antigen, thus anticipating said claims. See Abstract Wiedemann et al.


Conclusion

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ray Akhavan whose telephone number is 703-305-4454. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached at 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.


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